

REMARKS

This paper is submitted with a request and the fee for a one-month extension of time. Consequently, this is a full and timely response to the Final Office Action mailed by the U.S. Patent and Trademark Office on February 11, 2009. Claims 11, 22, 26 and 39-45 have been amended. Claims 1-10, 13-20, 24, 25 and 27-38 are canceled. Claim 46 is added. Claims 11, 12, 21-23, 26 and 39-46 are pending in the present application. The subject matter of amended claims 11, 22, 26 and 39-45 is illustrated in FIGs. 2A-2D, 3 and 4 and presented in the related detailed description of Applicants' original specification. The subject matter of new claim 46 is illustrated in FIG.s 2C, 7A & 7B and the related detailed description of Applicants' original specification. Therefore, no new matter is introduced.

In view of the foregoing amendments and following remarks, reconsideration and allowance of the present application and claims are respectfully requested.

Response to Claim Rejections under 35 U.S.C. §112, First Paragraph – Claims 11, 12, 21-23, 26 and 39-45

Claims 11, 12, 21-23, 26 and 39-45 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Office Action indicates that the claims require the optical system to “modify” incident light from one of the control area and the target area, which is not provided for by the instant specification.

Applicants have amended independent claim 11, such that the optical system is no longer required. Consequently, the rejection of claims 11, 12, 21-23, 26 and 39-41, which no longer require an optical system, is rendered moot.

Applicants have amended dependent claim 42, such that an optical system is positioned in a light path between the light source and at least one of the first and second photodetectors, the optical system arranged to process incident light from one of the control area and the target area. As indicated in item 2 of the Office Action, the instant specification teaches optical systems comprising a lens, chromatic prism, thin-film filters or diffractive gratings. Each of a lens, chromatic prism, thin-film filter or a diffractive grating arranged to receive incident light processes the incident light in a specific manner. Consequently, the instant specification provides adequate written

support for the claimed optical system. Accordingly, favorable reconsideration and withdrawal of the rejection of dependent claims 42-45 under 35 U.S.C. §112, first paragraph, are respectfully requested.

Response to Claim Rejections under 35 U.S.C. §103 – Claims 11, 12, 21-23, 26 and 39-45

A. Statement of the Rejection

Claims 11, 12, 21-23, 26 and 39-45 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S Patent Application Publication 20020004246 to Daniels et al. (hereinafter *Daniels*) in view of U.S. Patent No. 6,217,744 to Crosby (hereinafter *Crosby*).

B. Discussion of the Rejection

For a claim to be properly rejected under 35 U.S.C. § 103, the Examiner should set forth in the Office action: the relevant teachings of the prior art relied upon, the difference or differences in the claim over the applied reference(s), the proposed modification necessary to arrive at the claimed subject matter and an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. It is well settled law that a *prima facie* case of obviousness must teach or suggest all the claimed limitations.

Regarding the requirement to teach or suggest all the claim limitations, MPEP § 2143.03 states “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). ‘All words in a claim must be considered in judging the patentability of that claim against the prior art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants’ independent claim 11, as amended, includes at least one feature that is not disclosed, taught or suggested by the proposed combination of *Daniels* and *Crosby*. Specifically, the proposed combination fails to disclose, teach or suggest at least “a cap arranged to cover an opening in the single-use module to isolate the single

liquid sample, the single-use module having a terminal for receiving electrical power from a source external to the single-use module for the light source, the first photodetector, and the second photodetector, the terminal being part of an interface that is received in a receptacle of a reusable module, the terminal comprising conductors along an external surface of the single-use module, wherein application of the single liquid sample to the receiving zone of the test strip excludes the use of the light source, the first photodetector and the second photodetector disposed within the single-use module from being used to analyze an additional liquid sample different from the single liquid sample.”

Daniels discloses immunochromatographic test strip assays which employ semiconductor nanocrystals as detectable labels and methods for detecting and quantifying one or more analytes of interest in a test sample using the assays. *Daniels* is entirely silent regarding the claimed “cap arranged to cover an opening in the single-use module to isolate the single liquid sample.” In addition, *Daniels* is entirely silent concerning “a terminal for receiving electrical power from a source external to the single-use module for the light source, the first photodetector and the second photodetector.”

Crosby is cited for its alleged disclosure of features other than the claimed cap arranged to cover an opening in the single-use module to isolate the single liquid sample and the claimed terminal for receiving electrical power from a source external to the single-use module for the light source, the first photodetector and the second photodetector, the terminal being part of an interface that is received in a receptacle of a reusable module. In addition, *Crosby* does not remedy the failure of *Daniels* to disclose, teach or suggest at least these features of Applicants’ claimed test system.

Crosby discloses a device whereby power for the device comes from an electrochemical battery where a portion of the fluid sample itself becomes the electrolyte for the battery. Furthermore, the time of diffusion of the fluid into the battery provides the timing signal for activation of the system. Communication between the device and an information system is provided by a transponder system built into the device, which requires no direct electrical connection. (See *Crosby*, Abstract.)

Together, the proposed combination does not disclose, teach or suggest the claimed “cap arranged to cover an opening in the single-use module to isolate the single liquid sample, the single-use module having a terminal for receiving electrical power from a source external to the single-use module for the light source, the first photodetector, and the second photodetector, the terminal being part of an interface that is received in a receptacle of a reusable module, the terminal comprising conductors along an external surface of the single-use module, wherein application of the single liquid sample to the receiving zone of the test strip excludes the use of the light source, the first photodetector and the second photodetector disposed within the single-use module from being used to analyze an additional liquid sample different from the single liquid sample.” For at least this reason, the proposed combination fails to establish a *prima facie* case of obviousness with respect to Applicants’ claim 11. Accordingly, favorable reconsideration and withdrawal of the rejection of independent claim 11 under 35 U.S.C. §103(a) are respectfully requested.

Because independent claim 11 is allowable, dependent claims 12, 21-23, 26 and 39-45, which depend directly or indirectly from allowable independent claim 11, are allowable. *In re Fine, supra*. Accordingly, favorable reconsideration and withdrawal of the rejection of dependent claims 12, 21-23, 26 and 39-45 under 35 U.S.C. §103(a) are respectfully requested.

Applicants note that U.S. Patent No. 5,371,687 to Holmes II, et al. (hereinafter *Holmes*) *Holmes* was cited by the Office in an Office Action mailed November 27, 2007, as disclosing a terminal on an external surface of a single-use module. However, in contrast with *Holmes* which does not teach a single-use module, claim 11, as amended, includes a single-use module with a terminal comprising conductors along an external surface of the single-use module. *Holmes* does not disclose, teach or suggest conductors along an external surface of a terminal of a single-use module. Furthermore, *Holmes* does not remedy the failure of *Daniels* and *Crosby* to disclose, teach or suggest a “cap arranged to cover an opening in the single-use module to isolate the single liquid sample.”

New Claim 46

Because independent claim 11 is allowable, dependent claim 46, which depends directly from allowable independent claim 11, is also allowable. *In re Fine, supra*.

CONCLUSION

Applicants respectfully submit that pending claims 11, 12, 21-23, 26 and 39-46 are allowable and that the present application is in condition for allowance. Accordingly, a Notice of Allowance is respectfully solicited. Should the Examiner have any comments regarding the Applicants' response, Applicants request that the Examiner telephone Applicants' undersigned attorney.

Respectfully submitted,

**SMITH FROHWEIN TEMPEL
GREENLEE BLAHA LLC
D/B/A SENTRY LAW GROUP**

By: /Robert A. Blaha/
Robert A. Blaha
Registration No. 43,502
(770) 709-0069